Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The comparison of Clonidine and Granisetron in the prevention of postoperative shivering, nausea and vomiting.

Protocol summary

Summary

This double-blind randomized clinical trial on 100 patients with class 1 and 2 Anesthesiology admitted to hospitals of Babol University of Medical Sciences through easy sampling divided into two equal groups and alternate is performed after informed consent from patients Consciously. Inclusion criteria: elective orthopedic surgery; the patients ranged from 18 to 65 years; BMI (Body Mass Index) of less than 30 kg/m2 and a maximum of 2 hours of surgery time. Exclusion criteria: history of seizures; diabetes, Parkinson , motion sickness and migraine; psychotropic substances or sedatives drugs; addiction to alcohol or opoide; blood transfusion and that products; administration of vasoactive drugs during anesthesia; existence of active infection before anesthesia; receive any anti vomiting 48 hours preoperative; intra operative use of propofol; systolic blood pressure less than 90 or greater than 160 mmHg and patients with difficult intubation and body temperature less than 36 or more than 37.5 degrees centigrade. To a group of patients, will be a tablet 0/2 mg Clonidine with 50 ml of water and after 60 minutes will be induction of anesthesia. In the second group will administer Granisetron 40 mcg / kg intravenous immediately before induction of anesthesia and premedication, Induction and maintenance of anesthesia in both groups will be with the same conditions. Routine monitoring is utilized during anesthesia. Vital signs will be controlled at various intervals. Nausea, vomiting and shivering will be assessed and record based on criteria of measurement and the results are derived based on data analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205089684N1**

Registration date: **2012-06-23, 1391/04/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-23, 1391/04/03

Registrant information

Name

Ommelaila Rabiee Kenari

Name of organization / entity

Babol University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Clonidine and Granisetron in the prevention of postoperative shivering, nausea and vomiting.

Public title

The comparison of Clonidine and Granisetron in the prevention of postoperative shivering, nausea and vomiting.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: elective orthopedic surgery, the patients' age ranged from 18 to 65 years old; BMI (Body Mass Index) less than 30 kg/m2 and a maximum of 2 hours of surgery time. Exclusion criteria: emergency surgery; history of seizures, diabetes, Parkinson's or any other diseases that can cause shivering; motion sickness and migraine; history of psychotropic substances or sedatives drugs; addiction to alcohol or opoide; blood transfusion and that products, administration of vasoactive drugs during anesthesia; existence of active infection before anesthesia; receive any anti vomiting 48 hours preoperative; intra operative use of propofol; systolic blood pressure less than 90 or greater than 160 mmHg; patients with difficult intubation and body temperature less than 36 or more than 37.5 degrees centigrade

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences

Street address
Babol. gangafroz state .University of Medical Sciences babol

City
Babol

Postal code
47176

Approval date
2012-04-24, 1391/02/05

Ethics committee reference number
6266

Health conditions studied

1

Description of health condition studied
General anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nausea and vomiting

Timepoint
During recovery and world at the 6 hours

Method of measurement
The patients are assessed of the incidence of nausea and vomiting, by a trained individual which is not aware to administrate any drug, and then items to be recorded. Nausea will be assess and recorded base on feeling with the scale of a Multiple Choice without nausea, moderate and severe nausea. If patient can feel nausea at least 5 minutes it is considered an episode of nausea. The severe vomiting will be recorded base on without vomiting, once vomiting (mild), two or three occasions vomiting (moderate) and more than three times vomiting (severe). If there was between vomiting an interspaced at least one minute, each one of them is considered on episode vomiting. Meanwhile, retching can be considered equivalent to vomiting. In items that, patients had a severe nausea or twice vomiting and or the patient's own requests, are prescribed 8 mg Intravenous Metoclopramide as anti-nausea drugs supplemental.

2

Description
shiviring

Timepoint
The end of anesthesia and during recovery

Method of measurement
The shivering of patients will be evaluated after end anesthesia and during recovery with visual assessment scale, including: Zero =the cases without shivering, degree 1 = status of vasoconstriction and peripheral cyanosis without other cause (or straight hair, but without visible muscular activity), degree 2 = visible muscular activity confined to one muscle group (or mild fasciculation face and neck), degree 3= Visible, Shivering in more than one group of muscle, degree 4= Muscle activity visible that include all body. The items by a person trained and experienced and without the knowledge of the prescribed medicines will be assessed and are recorded in the relevant information. If grade of shivering was 3 or 4, the patient is treated with 25 mg

intravenous pethidine.

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled.
Method of measurement
Sphygmomanometer

2

Description
Core temperature (Tempan)
Timepoint
Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled
Method of measurement
Thermometer Tempanic

3

Description
Diastolic blood pressure
Timepoint
Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled.
Method of measurement
Sphygmomanometer

4

Description
Surface temperature (axillary)
Timepoint
Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled
Method of measurement
Thermometer's Axillary

5

Description
Heart rate
Timepoint
Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled
Method of measurement
Pulsoxymetri

Intervention groups

1

Description
Intervention group: Administration of Granisetron 40 mcg/kg intravenous immediately before induction of General Anesthesia.
Category
Treatment - Drugs

2

Description
Control group:A tablet 0.2 mg clonidine with 50 ml of water will be administered and performed induction of general anesthesia after 60 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
shahid Beheshti Hospital, Babol
Full name of responsible person
Doctor Ebrahim AliJanpour
Street address
Babol,Keshvari state
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Amrolah Mostafazadeh (Research Assistant)
Street address
Babol. Gangafroz,s state.
City
Babol
Grant name
49
Grant code / Reference number
1033
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Position
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Anesthesiologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty